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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,028	05/10/2001	Fei Yang	DEX-0146	7347

26259 7590 06/11/2003

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,028	YANG ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the claims 1-11 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. Claims 1-11 are improperly joined as the claimed methods require detection of distinct biological molecules, i.e., nucleic acids and proteins. A reference against one method would not be a reference against the other method. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

Restriction to one of the following inventions is required under 35 U.S.C. § 121 and 372:

I. Claims 1-6, drawn to methods of diagnosing lung cancer by detecting LSG nucleic acids.

II. Claims 1-6, drawn to methods of diagnosing lung cancer by detecting LSG proteins.

III. Claim 7, drawn to an antibody against a LSG nucleic acid.

IV. Claim 7, drawn to an antibody against a LSG protein.

V. Claims 8 and 9, drawn to methods of imaging using an antibody to a LSG nucleic acid.

VI. Claims 8 and 9, drawn to methods of imaging using an antibody to a LSG protein.

VII. Claims 10 and 11, drawn to methods of treatment antibodies to LSG nucleic acids.

VIII. Claims 10 and 11, drawn to methods of treatment antibodies to LSG proteins.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. However, inventions I and II do not share a common technical feature because the technical feature of each invention is distinct. That is, the technical feature of invention I is considered to be LSG nucleic acids, whereas the technical feature of invention II is considered to be LSG proteins. Nucleic acids and proteins are structurally and functionally distinct over one another. Proteins are composed of amino acids arranged in a specific order and having a specific 3-dimensional structure, whereas nucleic acids are composed of nucleotides arranged in a specific order. Proteins and nucleic acids are also utilized in different types of methods such that peptides may be used to generate antibodies whereas nucleic acids are used to synthesize other nucleic acids or may be used in hybridization assays. Further, inventions I does not share a special technical feature with inventions III and IV and invention II does not share a special technical feature with inventions III and IV because antibodies are structurally and functionally distinct over LSG nucleic acids and proteins. The amino acid sequence and 3-dimensional structure of LSG antibodies are distinct over the amino acid sequence and 3-dimensional structure of LSG proteins. Further, antibodies and proteins may be utilized in different types of methods, such that antibodies

may be used for therapeutic purposes and proteins may be used in assays to study gene expression levels.

It is noted that under 37 CFR 1.475(d) Applicant is entitled to an examination of the first product, method of making said product and method of using said product. In the instant Application, the methods of groups II and V-VIII constitute additional and distinct methods. Each of the claimed methods is also distinct over each other and have distinct special technical features because each method requires the use of distinct reagents, involves performing different method steps and have different objectives. In particular, the method of invention I requires using nucleic acid probes and/or primers and involves performing hybridization or amplification reactions to achieve the objective of diagnosing lung cancer. The method of invention II requires using proteins and involves performing Western blotting methods of ligand binding assays to achieve the objective of detecting LSG proteins as indicative of the occurrence of lung cancer. Inventions V and VI involves administering an antibody to a LSG nucleic acid or protein, respectively, to a patient and performing image analysis in order to achieve the objective of imaging lung cancer. Inventions VII and VIII require the use of LSG antibodies to nucleic acids and proteins, respectively and administering LSG antibodies to a patient in order to achieve the objective of treating lung cancer. Accordingly, the methods of groups II and V-VIII constitute additional and distinct methods.

Sequence Election Requirement Applicable to All Groups

In addition, each invention detailed above reads on patentably distinct inventions drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are structurally and functionally unrelated sequences, and a further restriction is applied to each invention. **In response to the restriction requirement, Applicant must further elect a single LSG sequence selected from the group consisting of SEQ ID NO: 1-5.** It is noted that it has been interpreted that the recitation in the claims of "LSG" refers to the sequences of SEQ ID NO: 1-5 (see page 7 of the specification: "What is meant by the levels of LSG as used herein, means levels of the native protein expressed by the genes comprising the polynucleotide sequence of any of SEQ ID NO: 1, 2, 3, 4 or 5").

It is noted that nucleotide sequences encoding different proteins and/or having distinct nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121 and 372. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

June 9, 2003

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER